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09/980,469	12/03/2001	Ziv Shani	01/22924	3374

7590 10/20/2004

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,469

Applicant(s)

SHANI ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26 and 28-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26, 28-30, 33 and 34 is/are rejected.
- 7) ☒ Claim(s) 31 and 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on December 3, 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This application filed December 3, 2001 is a national stage filing of PCT/IL00/00330, filed June 7, 2000, which is a continuation in part of 09/329,234, filed June 10, 1999, now US Patent 6,331,416.

Applicants' amendment filed August 5, 2004, has been received and entered. Claims 1-25, 27 have been cancelled. Claims 26 has been amended. Claims 29-34 have been added. Claims 26, 28-34 are pending and currently under examination.

Specification/Drawings

Upon review of the present disclosure it has been found that the nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825. 37 CFR 1.821(d) states: "[w]here the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description of claims, even if the sequence is also embedded in the text or the description or claims of the patent application. Specifically, neither the drawing nor the description of the drawings identifies the sequences set forth in the instant disclosure (see for example figures 2 and 4).

Appropriate correction is required.

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The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 28 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Amendments to claim 26 has obviated the basis of the rejection.

Newly amended claims 26 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, it is unclear how claim 29 further limits claim 26 since such signals would be required to accomplish the functional limitations added to claim 26.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(f) he did not himself invent the subject matter sought to be patented.

Claims 26, 28, stand rejected and newly added claims 30, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Shoseyov *et al.* (US Patent 5,670,623).

Claims 26, 28, stand rejected and newly added claims 30, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Shoseyov *et al.* (US Patent 5,719,044).

Applicants note the amendments to the claims and support in the specification for the instantly claimed invention (page 5). Applicants argue that instant invention is in contrast to the invention of '623 and '044 in that it requires specific compartmentalization of the fusion protein via a signal peptide (bridging pages 5-6). See Applicants' amendment, pages 5-6. Applicants arguments have been fully considered, but not found persuasive.

Review of the teachings of '623 and '044 and the allowed claims, it is noted that the fusion proteins contemplated and specifically recited in the claims are proteins that are present in cellular locations other than the cell wall. For example, glycosyltransferases are found and functional in the ER of eukaryotic cells. It is noted that the claims of '623 and '044 do not specifically recite compartmentalization, however the fusion proteins specifically claimed would result in compartmentalization of the fusion protein produced (see for example claim 8 of '044). Thus the teachings of both '623 and '044 anticipate the instant claims.

With regard to the remaining portions of the fusion protein Shoseyov *et al.* ('023) teach a CBD fusion protein that has a cleavable sequence between the CBD and the second portion of the fusion protein (see for example claim 6). The cleavable site can be affected both chemically and enzymatically (claims 7 and 8). Shoseyov *et al.* provide guidance for host cells including

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guidance for viral vectors and promoters to generate the fusion protein in a plant system.

Similarly, Shoseyov *et al.* ('044) teach a CBD fusion protein that has a cleavable sequence between the CBD and the second portion of the fusion protein (see for example claims 29 and 31). The cleavable site can be affected both chemically and enzymatically (claims 32 and 33).

Shoseyov *et al.* provide guidance for host cells including guidance for viral vectors and promoters to generate the fusion protein in a plant system.

Thus, for the reasons above and of record, the rejection is maintained.

Claims 26, 28-30, 33 and 34 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

Applicants argue that because the instantly claimed invention has been differentiated from that of US Patent 5,670,623 and 5,719,044, they can not be used in the basis of a 102(f) rejection. See Applicants' amendment, page 6. Applicants' arguments have been fully considered, but not found persuasive.

As argued above in the rejection made under 35 USC 102(b), the teachings of '623 and '044 anticipate instantly amended claims. Applicants have not provided any other arguments or details regarding the contribution of the inventorship, therefore the rejection is maintained for the reasons of record. In the instant case, the specification of both '623 and '044 contain teachings that anticipate the instantly claimed invention, however the inventive entity between the present application and that of '623 and '044 is different. The common inventor Shoseyov is noted, however there are several additional inventors that are listed in the issued patents while Shani is present on the instant application but not the issued patents. Importantly, the issued patents

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encompass methods that make obvious the instantly claimed product. It is noted that none of the issued claims specifically set forth that the host cell is a plant system, however the teachings in the specification of '623 and '044 provide clear guidance for this being one of the host cells contemplated. It is unclear given the similarity in guidance between the issued patents and the instant specification why the inventive entity differs, in particular since the instantly claimed product would be an obvious choice as a host cell in use of the patented methods.

Thus, for the reasons above and of record, the rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26, 28, stand rejected and newly added claims 30, 33 and 34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 5,670,623 and over claims 27-34 of U.S. Patent No. 5,719,044.

Applicants argue that amendment to the claims has differentiated the instantly claimed invention from that of '623 and '044, and that they can not be interpreted to be obvious since there is no specific recitation or requirement of compartmentalization in the claims of '623 and

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'044. See Applicants' amendment, page 7. Applicants' arguments have been fully considered, but not found persuasive.

Examiner notes that the claims of '623 and '044 do not specifically recite compartmentalization of the fusion protein, however the claims set forth specific fusion protein constructs such as glucosidases and transferases (claim 8 in '044 for example) which when expressed would be present in the endoplasmic reticulum or endosome, and would require these location for their appropriate enzymatic activity. Again, although the conflicting claims are not identical, they are not patentably distinct from each other because each patent is drawn to a method of protein production and isolation of a recombinantly generated CBD fusion protein. Though none of the claims specifically set forth that the host cell used to produce the CBD fusion protein is a plant cell, the specification provides detailed guidance for viral vectors and promoters for expression of the protein in plant systems making it one of the obvious choices for a host cell (see '623 column 15 and '044 column 14, for example).

Thus, for the reasons above and of record, the rejection is maintained.

Conclusion

No claim is allowed.

Claims 31 and 32 are free of the art of record because the art fails to teach or make obvious the use of the specific sequences set forth in these claims. These claims are objected to for being dependent on rejected claims, however would be found allowable if rewritten as independent claims incorporating all the limitations of the claims from which it depends.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

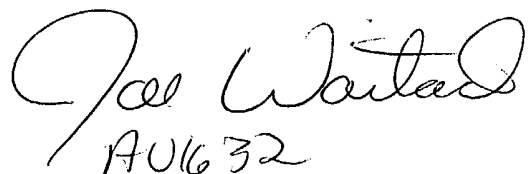
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach


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